

endoscopic fundoplication compares favorably because there were no deaths and only 1 report of pneumonia, although there were 3 wrap disruptions in almost half as many total patients as treated with laparoscopy in the aforementioned randomized series. Laine and colleagues<sup>26</sup> had also previously reported a prospective randomized study comparing laparoscopic with open Nissen fundoplication for patients with GERD and demonstrated no operative mortality and a mean hospital stay of 3.2 days for the laparoscopic group and 6.4 days for the open group. Our series is comparable, with no mortality and a mean hospital stay of 1.3 days.

Our initial experience with endoscopic fundoplication is currently limited to 46 patients. In addition, our follow-up is of short duration. Moreover, although there was a significant reduction in the number of patients who were still taking PPIs postoperatively, almost half of the treatment population is still taking PPIs, either at a lower dose or at least occasionally.

It is unlikely that endoscopic fundoplication will ever completely replace laparoscopic fundoplication because endoscopic fundoplication can only be used for patients with small or no hiatal hernias. However, if results prove to be durable, endoscopic fundoplication may become the procedure of choice for those patients who are candidates for this less invasive procedure. There may be other advantages that may make this approach preferable for patients with impaired esophageal motility.

In conclusion, we have demonstrated that endoscopic fundoplication is feasible, can be performed with a low incidence of complications, and is effective in a majority of patients at short-term follow-up. Further study is needed to define long-term outcomes and predictors of treatment success to optimize patient selection for therapy.

## References

1. American Gastroenterological Association. The burden of gastrointestinal diseases. Bethesda (MD): American Gastroenterological Association; 2001.
2. The American Gastroenterological Association Institute Medical Position Panel. American Gastroenterological Association medical position statement on the management of gastroesophageal reflux disease. *Gastroenterology*. 2008;135:1383-91.
3. Tytgat GN, McColl K, Tack J, Hotlmann G, Hunt RH, Malfertheiner P, et al. New algorithm for the treatment of gastro-oesophageal reflux disease. *Aliment Pharmacol Ther*. 2008;27:249-56.
4. Catania RA, Kavic SM, Roth JS, Lee TH, Meyer T, Fantry GT, et al. Laparoscopic Nissen fundoplication effectively relieves symptoms in patients with laryngopharyngeal reflux. *J Gastrointest Surg*. 2007;11:1579-88.
5. Westcott CJ, Hopkins MB, Bach K, Postma GN, Belafsky PC, Koufman JA. Fundoplication for laryngopharyngeal reflux disease. *J Am Coll Surg*. 2004;199:23-30.
6. Funch-Jensen P, Bendixen A, Iversen MG, Kehlet H. Complications and frequency of redo antireflux surgery in Denmark: a nationwide study, 1997-2005. *Surg Endosc*. 2008;22:627-30.
7. Hahnloser D, Schumacher M, Cavin R, Cosendy B, Petropoulos P. Risk factors for complications of laparoscopic Nissen fundoplication. *Surg Endosc*. 2002;16:43-7.
8. Hunter JG, Swanson L, Waring JP. Dysphagia after laparoscopic antireflux surgery. The impact of operative technique. *Ann Surg*. 1996;224:51-7.
9. Vakil N, Shaw M, Kirby R. Clinical effectiveness of laparoscopic fundoplication in a US community. *Am J Med*. 2003;114:1-5.
10. Cadiere GB, Rajan A, Rqibate M, Germay O, Dapri G, Himpens J, et al. Endoluminal fundoplication (ELF): evolution of EsophyX, a new surgical device for transoral surgery. *Min Invasive Ther Allied Technol*. 2006;15:348-55.
11. Velanovich V. Endoscopic, endoluminal fundoplication for gastroesophageal reflux disease: initial experience and lessons learned. *Surgery*. 2010;148:646-53.
12. Barnes WE, Hoddinott KM, Mundy S, Williams M. Transoral incisionless fundoplication offers high patient satisfaction and relief of therapy-resistant typical and atypical symptoms of GERD in community practice. *Surg Innov*. 2011;18:119-29.
13. Ben-David K, Carreras J, Lopes J. Are incisionless fundoplication procedures a safer alternative to the laparoscopic Nissen for the treatment of chronic gastroesophageal disease? *J Gastrointest Surg*. 2001;15:885-90.
14. Demyttenaere SV, Bergman S, Pham T, Anderson J, Dettorre R, Melvin WS, et al. Transoral incisionless fundoplication for gastroesophageal reflux disease in an unselected patient population. *Surg Endosc*. 2010;24:854-8.
15. Velanovich V. The development of the GERD-HRQL symptom severity instrument. *Dis Esoph*. 2007;20:130-4.
16. Hill LD, Kozarek RA, Kraemer SJ, Aye RW, Mercer DC, Low DE, et al. The gastroesophageal flap valve: in vitro and in vivo observations. *Gastrointest Endosc*. 1996;44:541-7.
17. Louis H, Deviere J. Endoscopic implantation of Enteryx for the treatment of gastroesophageal reflux disease: technique, preclinical and clinical experience. *Gastrointest Endosc Clin North Am*. 2003;13:191-200.
18. Cicala M, Gabbriellini A, Emerenziani S, Guarino MP, Ribolsi M, Caviglia R, et al. Effect of endoscopic augmentation of the lower oesophageal sphincter (gatekeeper reflux repair system) on intraoesophageal dynamic characteristics of acid reflux. *Gut*. 2005;54:183-6.
19. Torquati A, Richards WO. Endolumenal GERD treatments: critical appraisal of current literature with evidence-based medicine instruments. *Surg Endosc*. 2007;21:697-706.
20. Montgomery M, Hakanson B, Ljungqvist O, Ahlman B, Thorell A. Twelve months' follow-up after treatment with the EndoCinch endoscopic technique for gastro-oesophageal reflux disease: a randomized, placebo-controlled study. *Scand J Gastroenterol*. 2006;41:1382-9.
21. Pleskow D, Rothstein R, Kozarek R, Haber G, Gostout C, Al Lembo. Endoscopic full-thickness plication for the treatment of GERD: long-term multicenter results. *Surg Endosc*. 2007;21:439-44.
22. Fry LC, Monkemuller K, Malfertheiner P. Systematic review: endoluminal therapy for gastro-oesophageal reflux disease: evidence from clinical trials. *Eur J Gastroenterol Hepatol*. 2007;19:1125-39.
23. Jobe BA, O'Rourke RW, McMahon BP, Gravesen F, Lorenzo C, Hunter JG, et al. Transoral endoscopic fundoplication in the treatment of gastroesophageal reflux disease: the anatomic and physiologic basis for reconstruction of the esophago-gastric junction using a novel device. *Ann Surg*. 2008;248:69-76.
24. Hoppo T, Immanuel A, Schuchert M, Dubrava Z, Smith A, Nottle P, et al. Transoral incisionless fundoplication 2.0 procedure using EosphyX for gastroesophageal reflux disease. *J Gastrointest Surg*. 2010;14:1895-901.
25. Mahon D, Rhodes M, Decadt B, Hindmarsh A, Lowndes R, Beckingham I, et al. Randomized clinical trial of laparoscopic Nissen fundoplication compared with proton-pump inhibitors for treatment of chronic gastro-oesophageal reflux. *Br J Surg*. 2005;92:695-9.
26. Laine S, Rantala A, Gullichsen R, Ovaska J. Laparoscopic vs conventional Nissen fundoplication: a prospective randomized study. *Surg Endosc*. 1997;11:441-4.

## Discussion

**Dr W. Randolph Chitwood, Jr (Greenville, NC).** I think the next step should be a randomized study between a laparoscopic Nissen operation and this procedure. Do these patients have the same postoperative characteristics as those having a laparoscopic Nissen as far as failure to eructate?

**Dr Narsule.** They have very similar characteristics. They sometimes have postoperative bloating that we have been able to control with simethicone effectively thereafter.

**Dr Bryan Fitch Meyers** (*St. Louis, Mo*). There are some end points that are often talked about around antireflux surgery, both before and after. One is a DeMeester score or 24-hour pH monitoring. I did not see any data there or for manometry. Did you observe any objective manometric change or objective reduction in the DeMeester score after the implementation of this device?

**Dr Narsule.** In this study, we did not, because we did not deliberately have all of our patients undergo further studies. Simply put, after they followed up with us, we assessed the efficacy of the endoscopic fundoplication on the basis of their symptomatology and their response to the HRQL survey instrument. If there were issues of dissatisfaction or persistent symptoms, we worked them up. But aside from that, we did not perform any additional studies.

**Dr Meyers.** Moving forward, I think that would be an important thing to truly demonstrate the clinical effectiveness of this therapy. Patients who undergo this treatment want to get better, and there is going to be a certain measurable placebo effect. The self-reported quality of life and the rate of change in the use of PPIs are pretty soft end points for something that could have a potentially big utilization and cost associated with it.

**Dr G. Hossein Almassi** (*Milwaukee, Wis*). Nice work. I have 2 questions. How easy is it to do a redo after a failed endoscopy? Have you had any failures and did you do a redo endoscopic Nissen again?

**Dr Narsule.** The redo is very similar to the initial operation. We were fortunate to have information as to where the wrap had disrupted and, endoscopically, we were able to see the points of laxity that occurred after the first procedure. We were able to target where exactly to place the polypropylene H-fasteners. It was far easier than we had anticipated preoperatively.

**Dr Almassi.** I know gastroenterologists are not cardiologists, but what do you think will happen in the future? Are gastroenterologists going to be doing this procedure?

**Dr Narsule.** I do not think that the future of this procedure would be in the hands of the gastroenterologists alone, because I think that there is an increased complexity to performing a fundoplasty. There have been other endoscopic approaches to the treatment of GERD, and they have not persisted. Although they tried to decrease the compliance of the LES, perhaps because a fundoplasty had not fully been considered with those interventions, they were not durable. Adding a fundoplasty as part of the endoscopic approach requires the special perspective that the surgeon has in performing this procedure. Although it is an endoscopic procedure, it is a procedure that is performed along the same principles. I think that the results will be better and more durable in the hands of surgeons.

**Dr Toni Lerut** (*Leuven, Belgium*). I have a follow-up question on that. In Europe, the future is already in the hands of the gastroenterologists, because they are doing most of these procedures. It is so in our institution, but they do it together with us, and we do have a similar experience. What it shows on 24-hour pH monitoring is that this procedure decreases the volume of reflux, but it does not abolish it as efficiently as after a laparoscopic Nissen procedure. Would you advocate this type of procedure, for instance, in patients with Barrett's metaplasia?

**Dr Narsule.** For patients who do have Barrett's metaplasia, depending on whether it is dysplastic or not, I think that this procedure would still be very applicable. In fact, 5 of our patients had Barrett's esophagus, had an intervention for the metaplasia, and then subsequently underwent this procedure.